



ORGANISATION FOR ECONOMIC
CO-OPERATION AND DEVELOPMENT

ENVIRONMENT DIRECTORATE
Environment, Health and Safety Division

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Paris, 10 June 2009

To: Working Group of National Co-ordinators of the Test Guidelines Programme (WNT)

**SUBJECT: THE DRAFT REVISED LOCAL LYMPH NODE ASSAY (LLNA) TEST GUIDELINE 429 FOR
COMMENTS, AND INVITATION FOR NOMINATION OF NATIONAL EXPERTS TO AN EXPERT
CONSULTATION MEETING IN WASHINGTON DC 20-22 OCTOBER 2009**

Dear Madam/Sir,

Please find attached three new proposals for revised versions of the Local Lymph Node Assay (LLNA) Test Guideline 429 for your consideration. The new proposals are: (i) the traditional LLNA with added Performance Standards (PS), (ii), a non-radioactive LLNA test method called the “*DA-version*”, and (iii), a 2nd non-radioactive LLNA test method called the “*BrdU-ELISA version*”(project led by Japan and the USA).

The traditional LLNA (TG 429) offers an alternative (but not full replacement) to the TG 406 guinea pig tests and the new set of PS developed by US (ICCVAM) will allow the development of new or modified “me-too” tests. For definition of Performance Standards, please consult Guidance Document No. 34.

The proposed non-radioactive LLNA test methods have been developed and validated by Japan (JaCVAM and the Japanese Society for Alternatives to Animal Experiments) and the two test methods have been peer reviewed by Japan (JaCVAM) and the US (ICCVAM). The traditional LLNA includes the use of a radioactive component (¹²⁵I-iododeoxyuridine) in the procedure limiting the usability of the assay, since the use of radio-active components requires special laboratory safety arrangements. The two new proposals do not require the use of radio-labelled components and no other complicated apparatus and have been shown by the validation studies to perform equally good as the traditional TG 429.

The validation reports and the clean versions of the draft Test Guidelines are available on the Public Website: [http://www.oecd.org/document/55/0,3343,en_2649_34377_2349687_1_1_1_1,00.html#Draft_TG_for_Comment] Marked-up versions are available on the protected Website.

I would thereby like to invite National Co-ordinators to review the draft Test Guidelines. Your comments are requested **by the very latest 28 August 2009**, and if no comments are received the Secretariat considers this as silent approval to the present draft.

I also have the pleasure to announce an Expert Consultation Meeting to be held in Washington DC, USA on 20-22 October 2009. The meeting will be jointly hosted and supported by CPSC (US Consumer Product Safety Commission) and ICCVAM. The meeting venue is the CPSC, 4330 East West Highway, Bethesda, Maryland



20814. Information on meeting arrangements and logistical details will be made available on the protected meeting Website well ahead of the meeting.

As is usual practice, all government representatives are requested to announce their participation in the meeting through their permanent delegations to the OECD in Paris (see attached list for contact persons). The European Commission, BIAC and ICAPO representatives should register via their affiliation. For practical information, please contact Anna Söderström (anna.soderstrom@oecd.org).

Please don't hesitate to contact me if you have any questions or concerns.

Yours sincerely,

Patric Amcoff
Principal administrator
Environment, Health and Safety Division

Cc: European Commission (DGs Environment, Enterprise, Sanco, Science, JRC, ECVAM)
BIAC (including ACC, CEFIC, Croplife International, ECETOC, JCIA)
EEB, ICAPO, ILSI (Europe, HESI, North America), IPCS, UNECE, ILO, IFCS, TUAC
ENV Counsellors to OECD Permanent delegations